

EXHIBIT 16



8990 Springbrook Drive, Suite 100 • Minneapolis, MN 55433 • 612/785-2414 • Fax 612/785-9054

The Bair Hugger® Model 525 Lower Body blanket manufactured by Augustine Medical, Inc. has been developed to provide warm air therapy during surgery.

A test program was conducted measuring microbial contamination levels in the sterile field with and without the Model 525 Lower Body blanket and Bair Hugger® warming unit.

Product Design - The Bair Hugger® warming unit air intake draws room air through a microbially retentive HEPA filter. This is the same type of filter used for the air inlet to the operating suite. The machine produces an air flow of approximately 28 cubic feet per minute at a static pressure of 0.5 inches of water column. The warm air is ducted to the trunk of the Cardiac blanket via a standard equipment corrugated PVC hose. Air passes from the blanket via holes, and cascades over the underlying patient. Thus, room air which has been filtered upon entering the surgical suite is refiltered by the blanket system before being imparted to the patient.

Test system - Microbial measuring techniques were conducted on a surgical table in an operating suite. Tests for aerobic microbial colony forming units (CFU) were conducted using two collection methods. The first, the settling plate method, quantifies microbial CFU deposition rates per hour. The second method utilizes an Anderson single stage air sampler which provides quantitative measures of microbial CFU per ft³ of air.

Conclusions -

1. Data from both microbial sampling methods resulted in lower CFU levels with the non-sterile lower body blanket system in place. Anderson sample results demonstrated that CFU contamination levels were 4 times lower when the blanket was present.
2. The application of a Student's T-test (see attached statistical analysis) to the data shows no statistically significant difference in microbial contamination when comparing the room samples to the non-sterile Lower Body blanket samples.
3. Based on all available data, one can conclude the presence of the non-sterile lower body blanket DOES NOT increase microbial levels in the patient sterile field area.

TEST RESULTS**Sampling Plate Microbial
CFU Contamination Count**

	Room	Under Non-Sterile Lower Body Blanket
	1	3
	1	0
	0	2
	0	1
	0	4
	0	3
	2	0
	3	0
	5	4
Total CFUs	12	17
Avg/Plate/30 min	1.3	1.9
Plate Count Range	0-5	0-4
Std. Deviation	1.6	1.6
$\bar{x}+3$ std. dev.	6.10	6.70

**Anderson Air Sampler
CFU Contamination Counts**

	Room	Under Non-Sterile Lower Body Blanket
	27	5
	7	3
	22	5
Total CFUs	56	13
No. of Samples	3	3
Avg/plate	18.7	4.3
Range	7 to 27	3 to 5
Std. Deviation	8.5	0.9
$\bar{x}+3$ std. dev.	44.16	7.16

The term $\bar{x}+3$ std. dev. is used to calculate the maximum number expected in a very large sample size from a given population.

Gregg A. Mosley 10/25/96
 Gregg A. Mosley Date
 President